III. REMARKS

Claims 84-103 are pending. Claims 60-83 have been cancelled without prejudice by virtue of this amendment.

Support for the language in new independent claims 84, 94, 102 and 103 directed to a controlled release formulation comprising at least one HMG-CoA reductase inhibitor is found throughout the specification, particularly at pages 10-31. The language in the new independent claims directed to "oral administration" is supported, e.g., at page 10 lines 14. The language in the new independent claims directed to the release of the at least one HMG-CoA reductase inhibitor at a rate suitable to maintain therapeutically effective levels over a 24 hour dosing interval is found, e.g., at page 12, lines 3-8, the formulation information at pages 10-31, example 4 (pages 39-41), and Figure 7. Support for the dependent claims can be found throughout the specification, and in particular as follows. Support for the phrase "*at least* 18 pg/ml after 1 month of treatment" is found in example 4, due to the test results in example 4 including placebo which would necessarily make the level *greater than* 18 pg/ml in humans who were administered the Lovastatin XL product (rather than placebo).

Support for new claim 85 is found, e.g., at page 12, lines 1-2.

Support for new claim 86 is found, e.g., at page 12, lines 1-2.

Support for new claim 87 is found, e.g., at page 9, lines 10-19, and original claim 5.

Support for new claim 88 is found, e.g., in original claim 6.

Support for new claim 89 is found, e.g., at page 11, lines 3-7.

Support for new claim 90, is found, e.g., at page 2, lines 18-20, and page 4, lines 22-24.

Support for new claim 91 is found, e.g., at page 12, line 20 to page 13, line 2 and in the examples.

Support for new claim 92 is found, e.g., at page 11, lines 3-7.

Support for new claim 93 is found, e.g., in original claim 6.

Support for new claim 95 is found, e.g., at page 11, lines 3-7.

Support for new claim 96 is found, e.g., at page 1, lines 12-14, and page 4, line 22 to page 5, line 3.

Support for new claim 97 is found, e.g., in original claim 6.

Support for new claim 98 is found, e.g., at page 11, line 21 to page 12, line 2.

Support for new claim 99 is found, e.g., at page 12, lines 1-2.

Support for new claim 100 is found, e.g., at page 11, lines 3-7.

Support for new claim 101 is found, e.g., page 12, line 20 to page 13 line 2 and in the examples.

It is respectfully submitted that no new matter has been added by virtue of this amendment.

A. Rejection of claims 60-83 under 35 U.S.C. § 102

Claims 60-83 were rejected under 35 U.S.C. 102(b) "as being anticipated by Scolnick (WO 95/06470)." The Examiner states that "Scolnick discloses methods of treating Alzheimer's disease or the onset of Alzheimer's disease in a human patient comprising administering to the said patient a therapeutically effective amount of a composition comprising an HMG-CoA reductase inhibitor, such as lovastatin, simvastatin, pravastatin, and fluvastatin." The Examiner further states that "Scolnick also discloses that the HMG-CoA reductase inhibitor is administered by a controlled release dosage form, and notes that "the therapeutically effective amount of the HMG-CoA reductase inhibitor to be administered per day in the instant invention is also disclosed in Scolnick." The Examiner also states that "Scolnick discloses that a drug that affects brain vasculature is useful in methods of treating Alzheimer's disease as well. See abstract, page 2 lines 16-20, page 10, and claims 1-25." The Examiner concludes that "Scolnick's method inherently treats or reduces beta amyloid levels in a human which exhibits symptoms of Alzheimer's disease, as claimed herein since Scolnick's method steps are same as the instant method steps. See Ex parte Novitski, 26 USPQ2d 1389," and that "Scolnick clearly anticipates the claimed invention herein."

Claims 60-83 have been cancelled without prejudice and replaced with new claims 84-103.

New independent claims 84, 94, 102 and 103 call for, inter alia, orally administering a controlled release formulation comprising at least one HMG-CoA reductase inhibitor which after oral administration to a human patient releases said at least one HMG-CoA reductase inhibitor at a rate suitable to maintain therapeutically effective levels over a 24 hour dosing interval, and continuing treatment with said controlled release formulation to effect a decrease in mean beta amyloid concentration in the blood of said human patient by at least about 18 pg/ml after 1 month of treatment. It is respectfully submitted that Scolnick et al. fail to teach these limitations, and therefore cannot anticipate the new claims.

With respect to the Examiner's rejection of the prior claims based on the position that "Scolnick's method inherently treats or reduces beta amyloid levels in a human which exhibits symptoms of Alzheimer's disease...since Scolnick's method steps are same (sic) as the instant method claims", this rejection is respectfully submitted to be inapplicable to the newly presented claims. First, Scolnick does not exemplify administration of a *controlled release formulation*.[1] Second, Scolnick does not teach a decrease in mean beta amyloid concentration in the blood of said human patient by at least about 18 pg/ml after 1 month of treatment. In accordance with the present invention, a controlled release formulation of the HMG-CoA reductase inhibitor is utilized to provide an enhanced effect that *cannot be achieved* by conventional immediate release dosing (See, e.g., page 12, lines 3-5). It is respectfully submitted that, with the above in mind, there is no objective basis to characterize Scolnick's exemplified administration of 20 mg immediate release lovastatin or 40 mg immediate release simvastatin per day will inherently have the same effect as controlled release formulations as presently described and claimed. Further, Scolnick does not anticipate the present invention because there is no description in Scolnick of the benefits of controlled release formulations and because Scolnick did not test controlled release formulations.

In view of the reasons set forth above and others, it is respectfully submitted that Scolnick does not anticipate the claims and the rejection should be removed.

[1] Scolnick at page 11 does mention the possibility of oral administration of the medicament "in the form of a time-controlled release vehicle" at page 11, lines 8-15.

Further, Scolnick fails to teach the claimed step of "determining whether a human has an APP processing disorder" (claim 84) or "determining whether a human exhibits an elevated level of β-amyloid" (claim 102).

The Examiner's attention is also respectfully directed to claim 103, which is directed to the treatment of Down's Syndrome. Scolnick, et al. do not teach a method for treating Down's Syndrome in humans, and it is respectfully submitted that this claim is patentable over Scolnick, et al.

B. Conclusion

It is now believed that the above-referenced rejection has been obviated and withdrawal is respectfully requested. It is believed that all claims are now in condition for allowance.

An early and favorable action on the merits is earnestly solicited.

Respectfully submitted,
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